#6
OC
6-18-03
Subspec

TITLE OF THE INVENTION

Endotracheal Tube With Aerosol Delivery Apparatus.

Applicant Number One: Sunil Dhuper, MD

Citizenship: US

Residence: 47, Red Ground Road, Old Westbury, New York 11568

Applicant Number Two: Sarita Dhuper, MD

Citizenship: US

Residence: 47, Red Ground Road, Old Westbury, New York 11568

CROSS-REFERENCE TO RELATED APPLICATIONS

3114373	Jun., 1962	Anderson	604/45
3173418	Mar., 1965	Baran	128/207
3638655	Feb., 1972	Doherty	125/207
3788326	Jan., 1974	Jacobs	128/207
3981299	Sept., 1976	Murray	604/43
4022219	May, 1977	Basta	128/207
3173418	May, 1977	Baran	128/207
4119101	Oct., 1978	Igich	128/202
4214592	Jul., 1980	Imbruce	600/556
4327720	May, 1982	Brunson et al	128/207
4417576	Nov., 1983	Baran	128/207
D272094	Jan., 1984	Wolf et al	D24/110
4453545	Jun., 1984	Inoue	128/207
4569344	Feb., 1986	Palmer	128/207
4584998	Apr., 1986	McGrail	128/207
4607635	Aug., 1986	Heyden	128/207
4637389	Jan., 1987	Heyden	128/207
4674495	Jun., 1987	Orr	128/207
4669463	Jun., 1987	McConnell	128/207
4693243	Sept., 1987	Buras	128/207
D307183	Apr., 1990	Kalayjian	D24/110
4955375	Sept., 1990	Martinez	128/207
4977894	Dec., 1990	Davies	128/207
5029580	Jul., 1991	Radford	128/207
D328244	Jul., 1992	Hamilton et al	D9/338
5146916	Sept., 1992	Catalani	128/207

D335175	Apr., 1993	Sladek	D24/110
5513630	May, 1996	Century	128/203
5542412	Aug., 1996	Century	128/203
5570686	Nov., 1996	Century	128/203
579758	Jan., 1997	Century	441/60
5594987	Jan., 1997	Century	29/890
5606789	Mar., 1997	Century	29/281

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not Applicable

REFERENCE TO A SEQUENCE LISTING, A TABLE, OR A COMPUTER PROGRAM LISTING COMPACT DISK APPENDIX

Not Applicable.

BACKGROUND OF THE INVENTION

The present invention relates to medical-surgical devices for intubation i.e. endotracheal tube (ET tube) intended for tracheal insertion in patients requiring mechanical ventilation. This tube is specifically designed for effective intrapulmonary deposition of aerosol particles-quantitatively as well as qualitatively (uniform distribution in tracheobronchial tree) in patients on mechanical ventilation via endotracheal tube. Many therapeutic substances can be utilized through this route, to name a few, bronchodilators, anti-inflammatory agents like steroids, antibiotics, anticholinergics, heparin, surfactant, antiproteases, gene transfer products, etc.

The advantages of intrapulmonary drug delivery as opposed to systemic administration are well known. Multiple medications as outlined above readily lend themselves for pulmonary administration. Current methods of drug administration to the lungs are inefficient. Not only are they limited in delivery of quantitatively significant amount of medication to the lungs, but they have also failed qualitatively to achieve uniform intrapulmonary distribution.

There are two methods currently available for intrapulmonary drug delivery.

(I) Liquid bolus: The medication is instilled in the form of liquid bolus via a bronchoscope or through an endotracheal (ET) tube. Not only is the distribution by this method non-uniform but there is also a significant risk of inducing respiratory distress and hypoxemia.

(II) Aerosol Inhalation: Methods employed use Metered Dose Inhalers (MDI's) with low boiling point propellants such as chlorofluoroalkanes or aerosol particles generated by heat, traditional compressed air nebulizers, or ultrasonic nebulizers. This method, even though it produces a more uniform distribution of aerosol particles compared with liquid bolus method, is limited in quantitatively delivering significant amount of medication to the lungs. Only a small fraction of the medication reaches the lungs and majority of the aerosol particles either adhere to the nasal passages and oropharynx or are exhaled out. Efficiency of aerosol delivery drops down even further in patients who are intubated and require mechanical ventilation. Beck et al found that inhalation of nebulized material through an endotracheal tube resulted in deposition of only 1.87% of the delivered particles to the lungs. Methods employing a combined ventilator dispenser and adapter (U.S. Patent 335.175) with MDI's have revealed equally poor results because much of the aerosol particles adhere to the ET tube and the inspiratory limb of the corrugated plastic tube.

Investigators over the years have devised numerous endotracheal tubes for intrapulmonary drug delivery. Most designs of endotracheal tubes so far have only addressed the issue of drug delivery in the form of liquid bolus by incorporating drug irrigation devices in the traditional ET tube either in the form of secondary canalization with multiple micrometric openings (U.S. Patent 5146936) or with some such modification of the original design.

Generation and delivery of aerosol particles with small mid-mean diameter, which is critical for uniform deposition in the tracheobronchial tree especially to reach the small airways, has not been addressed by any of the currently existing endotracheal tubes incorporating drug irrigation devices. Recently one of the investigators invented a delivery device for intra-tracheal administration of drug in aerosol form called 'Penn Century Intra-tracheal Aerosolizer (Microsprayer)' [U.S. Patent No.'s 5579758,5594987,5606789, 5513630, 5542412, 5570686]. This device is not related to our field of invention i.e. medical surgical devices for intubation. The clinical utility of this device in humans at this time is extremely limited because of its high cost and need for sterilization after every use and as such it is solely being used as a research tool.

AMENDMENTS TO THE BRIEF SUMMARY OF THE INVENTION

Objects of Invention

The main object of the present invention is to provide a modified ET tube that serves the following purposes:

- Aerosol drug delivery to tracheobronchial tree.
- Generation and delivery of aerosol particles at the distal end of the ET tube with mid mean diameter that will allow uniform distribution throughout the tracheobronchial tree.
- Generation and delivery of aerosol particles at the distal end of the ET tube so as to quantitatively deliver significant fraction of the generated aerosol particles to the tracheobronchial tree without adherence to the ET tube. This also implies cost effectiveness by preventing waste of medication.
- Simple inexpensive method of intrapulmonary drug delivery
- To achieve all the previous mentioned objects without interfering with the function of the ET tube.
- To achieve the above objectives through a device that does not impede intubation or in anyway make it more complicated for the operator, or more traumatic to the patient.

The defined objects are obtained through our invention i.e. the ET tube that incorporates the following new features:

- External Medication Dispenser with Adapter (MDA) – An external MDA is attached to the ET tube at it's proximal end. The adapter is specifically designed such that the outer circumference of a cylindrical valve stern located at the end of a conventional metered dose inhaler (MDI) canister perfectly fits into the inner circumference of the cylindrical frame work of MDA. Aerosol particles are generated from a nozzle located at the distal end of the valve stern on actuation of the MDI canister. The use of an MDI for intrapulmonary delivery of various medications is well known. An MDI consists of a pressurized canister containing powdered medication with a low boiling point propellant maintained in liquid state. When the valve of the MDI is activated, the propellant is released and forces medication from the nozzle of the canister along with propellant. Since the essence of this invention disclosed herein does not relate specifically to the structure of an MDI device, the details of this construction will not be discussed herein. Means of making and using MDI are well known to those skilled in the art. The MDA tapers at its distal end to reach an inner diameter (ID) of a pinhole

(range 0.1mm-1.0mm). A secondary cannula originates from the distal end of the MDA, the two fused or mated to each other. This feature of our invention differentiates it from most of the other existing adapters that have a pinhole opening on one of the sides, a few millimeters proximal tube the distal end of the valve stem which is generally closed or is a blind end.

- Secondary cannula (semi-flexible part)- Originating from the distal end of the MDA is a semi-flexible cannula. The ID of the cannula may be the same as the ID of the pinhole opening at the distal tip of the MDA. The cannula can vary in length (generally < 10cm) depending on the size of the ET tube, adult or pediatric. The semi-flexible cannula enters into the wall of the ET tube through an opening on the outer annular surface of the ET tube. The point of entry of the secondary cannula is on the outer lateral surface of the ET tube compared with the primary cannula for the balloon cuff which enters on the convex surface, so as not to make intubation complicated for the operator. Note that the semi-flexible cannula could be made semi-rigid by increasing the thickness of its wall and using a stiffer plastic material without changing the ID.
- Secondary canalization (rigid part)- The termination of secondary cannula on the outer annular surface of the ET tube marks the origin of a secondary canalization. The secondary canalization is dispose for 100% of its course between the outer annular surface and the inner annular surface in the wall of the ET tube. The secondary canalization terminates at its distal end as a pinhole opening at the tip of the ET tube. The ID of the secondary canalization may be the same as the ID of the flexible part of secondary cannula. The course of the secondary canalization from its proximal end to its distal end within the wall of the ET tube is from the outer annular surface to the inner annular surface. The narrow lumen of the secondary cannula and secondary canalization allows the particles generated by MDI to reach the distal tip of the ET tube in aerosol form without adherence to the inner surface of the ET tube.

AMENDMENTS TO THE BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING

Further features of the present invention will become apparent in the accompanying drawings as well as the detailed description of the preferred embodiments.

Fig 1 shows the longitudinal length of the ET tube incorporating all the features described in the summary of the invention i.e. MDA, secondary cannula (semi flexible part) outside the main body of the ET tube and the secondary canalization (rigid part) disposed within the wall of the ET tube.

Fig 2 shows the longitudinal length of the ET tube associated with alternative embodiment of secondary canalization.

Figs 3a,3b,3c and 3d show a cross section of the ET tube (Fig 1) taken at four levels.

Fig 3a- cross section at level 1 (L-L_1)

Fig 3b-cross section at level 2 (L-L_2)

Fig 3c-cross section at level 3 (L-L_3)

Fig 3d-cross section at level 4 (L-L_4)

Figs 4a,4b,4c and 4d show a cross section of the ET tube (Fig 2) taken at four levels.

Fig 4a cross-section at level 5 (L-L_5)

Fig 4b cross-section at level 6 (L-L_6)

Fig 4c cross-section at level 7 (L-L_7)

Fig 4d cross-section at level 8 (L-L_8)

Figs 5a, 5b, 5c, and 5d show the perspective views of the MDA.

Fig 5a shows the oblique view of the MDA

Fig 5b represents the front and rear elevational view

Fig 5c represents the left and right elevational view

Fig 5d represents the cross section (top and bottom views)

AMENDMENTS TO THE DETAILED DESCRIPTION OF THE INVENTION

Fig 1 shows the longitudinal length of an ET tube which is composed of an elongated hollow tube (1) approximately 34cm long made of plastic material. The internal diameter of the tube could vary from 2.5 mm to 10.0mm and the external diameter could vary from 3.5 mm to 13mm. The thickness of the wall of the tube could vary from 0.5 mm to 2.0 mm. The tube is a flexible elongated conduit with a concave surface on one side and a convex surface on the opposite side. It's proximal is end connected to an adapter (2) which enables it to be connected to an elongated tube of a mechanical ventilator. The distal end has a 4cm expandable cuff (3) starting approximately 4cm from the distal tip and ending approximately 8cm from the distal tip. In the distal 4 cm of the ET tube, between the expandable cuff (3) and the distal tip of the ET tube, there is a pair of oval holes (4) one each on the opposite surfaces of the tube facing each other. The size of the holes can vary between 5mm and 1cm. A small tube i.e. primary canalization (5) of approximately 1mm diameter runs within the wall on the convex side of the tube(s) and is connected to the expandable cuff (3) for inflation and deflation by terminating on the outer surface of the ET tube as a 1mm hole (7). This canalization can alternatively be attached on the outer surface of the tube on the convex side. This primary canalization (5) is fused to a semi-flexible primary cannula (8) (approximately 18cm from the distal tip of a 34 cm long ET tube) which continues outside and adjacent to the main tubular structure of the ET tube (1). The semi-flexible part starts at approximately 18 cm from the distal tip of the ET tube and continues proximally for a few centimeters to terminate into a cuff inflation indicator (9) and adapter (10) for a syringe. The connection between the semi-flexible primary cannula (8) and primary canalization (5) is through an opening (6) on the outer surface of the ET tube (1). The opening (6) is also 1mm in ID. On the lateral surface, through an opening (13) on the outer surface of the ET tube, at the same level as the opening (6) or at a higher level, there originates a secondary canalization (11) that is disposed in the wall of the ET tube. The ID of this secondary canalization can vary from 0.1 mm to 1.0 mm in size. This secondary canalization continues distally beyond the expandable inflatable cuff (3) to terminate as a pinhole opening (12) at the distal tip of the ET tube. The course of the secondary canalization within the wall of ET tube is from the outer annular surface to the inner annular surface and it terminates near the inner annular surface at the distal tip of the ET tube. The secondary canalization (11) is an extension of a semi-flexible secondary cannula (14) which continues outside and adjacent to the main tubular structure of the ET tube (1) without adhering to it just like the semi-flexible primary cannula (8). The semi-flexible secondary cannula (14) makes a connection with the secondary canalization (11) through the opening (13) on the

outer surface of the ET tube. The semi-flexible secondary cannula (14) is fused or mated to a medication dispenser with adapter (15) at its proximal end. The adapter of MDA (15) is designed to fit a valve stem of a metered dose inhaler (MDI) canister.

Fig 2 shows the longitudinal view of the ET tube associated with alternative embodiments of secondary canalization. Fig 2 is the same as Fig 1 but with an additional secondary canalization (16) running a course similar to the secondary canalization (11) in the wall of the ET tube (1) but on the opposite lateral surface. The additional secondary canalization (16) is disposed between the outer annular surface and the inner annular surface in the wall of the ET tube (1) and continues distally like secondary canalization (11) to terminate as a pinhole opening (17) at distal tip of the ET tube (1). The additional secondary canalization (16) is an extension of an additional semi-flexible secondary cannula (18), the two fused or mated through an opening (19) on the outer lateral surface of the ET tube (1). The proximal end of the additional semi-flexible secondary cannula (18) is fused or mated to the distal part of a second MDA (20), designed to fit a valve stem of a metered dose inhaler (MDI) canister. Note that the additional semi-flexible secondary cannula (18) can also be made semi-rigid while keeping all other parts and connections the same. In this respect the length of the additional secondary cannula (18) outside the main tubular structure could be shortened and the additional secondary canalization (16) in the wall of the ET tube (1) could be elongated.

Figs 3a, 3b, 3c and 3d show details of 4 cross sections at 4 levels of the ET tube as shown in Fig 1.

Fig 3a is the cross section at level L-L1which shows a lumen (1), a wall (2), an inner annular surface (3a), and an outer annular surface (3b) of the ET tube.

Fig 3b is the same as Fig 3a but with the appearance of a secondary canalization (4) disposed between the outer annular surface (3b) and the inner annular surface (3a) of the wall (2) of the ET tube. The secondary canalization (4) is disposed closer to the outer annular surface (3b).

Fig 3c is the same as Fig 3b but with a difference in the position of the secondary canalization (4) which is now disposed in the center of the wall (2). Also there is an additional primary canalization (5) disposed between the outer annular surface (3b) and the inner annular surface (3a) on the convex side in the wall (2) of the ET tube.

Fig 3d is the same as Fig 3c but with the absence of the primary canalization (5) as it terminates at a higher level near the expandable cuff (not demonstrated here, but shown as character 3 in Figs. 1 and 2). The secondary canalization (4) is now closer to the inner annular surface (3a) of the wall (2) of the ET tube.

Figs 4a, 4b, 4c and 4d show details of 4 cross sections at 4 different levels as seen in Fig 2

Fig 4a is the same as Fig 3a

Fig 4b is the same as Fig 3b but with an additional secondary canalization (6) disposed between the outer annular surface (3b) and inner annular surface (3a) of the wall of the ET tube on the side contralateral to the secondary canalization (4).

Fig 4c is the same as Fig 3c but with an additional secondary canalization (6)

Fig 4d is the same as Fig 3d but with an additional secondary canalization (6)

Note that the tracks of both the secondary canalizations (4, 6) in the wall (2) of the ET tube run from the outer annular surface (3b) to the inner annular surface (3a) of the ET tube. The primary canalization (5) stays towards the outer annular surface (3b) all through its course in the wall (2) of the ET tube. It is obvious that the shape and location of the primary and secondary canalizations can be different from those illustrated above subject to the purpose of invention. The canalizations can continue on or near the outer annular surface or on or near the inner annular surface of the wall (2) of the ET tube or could alternatively run partly on the inner annular surface (3a) and/or outer annular surface (3b) and partly disposed in the wall (2) of the ET tube.

Fig 5a is the oblique view of a medication dispenser with adapter (MDA) which is cylindrical in configuration. The inner circumference of the MDA decreases progressively from the proximal part (1) to the distal part (2). The inner circumference of the proximal part (1) of the MDA is designed to fit the outer circumference of a valve stem of a metered dose inhaler (MDI) canister. The inner circumference of the distal part (2) of the MDA decreases progressively for 1-2 mm along it's distal course to reach a pinhole opening (3) at it's distal tip which marks the origin of a semi-flexible secondary cannula (4) {also described as (14) and (18) in Fig 1 and 2 respectively.} Wrapped around the proximal part (1) and the distal part (2) of the MDA is a central circular plate (5) with two side handles, one handle (6) for the index finger and the other handle (7) for the middle finger. The handles (6, 7) help to hold the MDA steady when pressure is applied with the thumb to depress the valve stem of the MDI canister in order to actuate the valve.

Fig 5b represents the front and rear elevational views of MDA described in Fig 5a.

Fig 5c represents the left and right elevational views of MDA described in Fig 5a.

Fig 5d represents the cross-section (top and bottom views) of MDA described in Fig 5a. The wall of the proximal part (1), the wall of the distal part (2), and the pinhole opening (3) of the distal part (2) and the circular plate (5) of the MDA are demonstrated in Fig. 5d. The opening (3) marks the origin of the semi-flexible secondary cannula (described as (4) in Fig 5a). The two circles each for proximal part (1) and distal part (2) in Fig. 5d represent the progressively decreasing inner circumference when moving from the proximal to the distal end of the MDA.

It is noted that the illustration (drawings) and description of the preferred embodiments have been provided merely for the purpose of explanation and although the invention has been described herein with reference to particular means, materials and embodiments, the invention is not intended to be limited to the particulars disclosed herein; rather the invention intends to all functionally equivalent structures, methods and uses such as are within the scope of the appended claims.